

## **REMARKS**

Claims 1, 3-12, 14-22, and 24-30 remain in the application. No additional claims fee is due.

### **Invention Synopsis**

The present invention is directed to a liquid nutritional formula, containing Vitamin D and extensively hydrolyzed protein with a degree of hydrolysis of at least about 20%, aseptically packaged in a plastic container, which results in a surprisingly reduced rate of Vitamin D degradation. The invention is also directed toward a method of making the formula.

### **REJECTION UNDER 35 USC 103(a)**

Claims 1, 3-12, 14-22, and 24-30 have been rejected under 35 USC 103(a) as being unpatentable over Girsh (5,204,134) or Cope (5,480,872) or Hill (5,382,439) in view of Lien (US 2004/0062849). The Examiner contends that it would have been obvious to incorporate the hydrolyzed protein of Lien (with a defined DH/degree hydrolysis) into the nutritional formulations disclosed by any one of Girsh, Hill, or Cope, to thereby realize the claimed invention. Applicant respectfully traverses this rejection.

Applicant maintains that the presently claimed embodiments of the invention are patentable over Girsh, or Cope, or Hill, in view of Lien, for the following reasons and those previously of record.

Applicant conducted a study and found, surprisingly, that the shelf-life stability of Vitamin D can be improved, even when formulated in the presence of extensively hydrolyzed protein, provided that the formula is aseptically packaged in plastic containers rather than retort packaged in metal containers (Applicant's specification, p. 3, lines 9-15; p. 15, lines 6-11 and 14-21). In the last Office Action, the claims were amended to emphasize aseptically packaged *plastic* containers, rather than *any* aseptically packaged container.

The Examiner contends, however, that Applicant studied and reported results for product that was aseptically packaged in dark containers, not plastic containers; therefore,

Applicant has provided no data to support that the use of plastic containers provides better results than the use of other types of containers.

Applicant respectfully disagrees. Applicant conducted a study and compared the vitamin stability of a retort packaged liquid nutritional formula to an aseptically packaged liquid nutritional formula (Applicant's specification, p. 14, lines 20-22). Tables II-VII contain the vitamin results, over shelf life, for the retorted and aseptic samples. Contrary to the Examiner's contention, all aseptic samples were packaged into 32 ounce *plastic* bottles (Applicant's specification p. 15, lines 6-11 and 14-21). As a result, Applicant's surprising finding, that the shelf-life stability of Vitamin D can be improved in an extensively hydrolyzed protein formulation, is specific to product that is aseptically packaged into *plastic* containers.

In short, none of the references, taken alone or in combination, disclose or suggest aseptic packaging for the purpose of reducing the rate of Vitamin D degradation in an extensively hydrolyzed protein formulation, and certainly none suggest the stability benefits made possible by Applicants selection of a *plastic* package for such a formulation.

In view of the foregoing remarks, Applicant respectfully requests withdrawal of this rejection.

#### **Conclusion**

Applicant respectfully requests reconsideration of this application and allowance of claims 1, 3-12, 14-22, and 24-30.

Respectfully submitted,

By William J. Winter  
Attorney for Applicant  
Registration No. 36,060

Ross Products Division of  
ABBOTT LABORATORIES  
Department 108140/S1  
625 Cleveland Avenue  
Columbus, OHIO 43215-1724  
Phone (614) 624-5686; Fax (614) 624-3074